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I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

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Signed Andrew Gersey

Dated 22 September 1999

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

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1. Your reference AM/DIL 1

2. Patent a
(The Pate
9816800.8 3 AUG 1998

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ANTHONY WALTER ANSON
101, MARTINDALE ROAD
HOUNSLOW
MIDDLSX TW4 7EZ

Patents ADP number *(if you know it)* 38102310 01

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

A DILATOR

5. Name of your agent *(if you have one)* N/A

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

ANSON MEDICAL LIMITED
THE INNOVATION CENTRE
68 MILTON PARK
ABINGDON OX14 4RX

Williams, Powell & Associates
4 St Paul's Churchyard
London
EC4M 8AY

Patents ADP number *(if you know it)* 6847164002

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
N/A		

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*
N/A	

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

N/A

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	5
Claim(s)	
Abstract	
Drawing(s)	4

10. If you are also filing any of the following, state how many against each item.

Priority documents	~~NIL~~ 1
Translations of priority documents	" "
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	" "
Request for preliminary examination and search *(Patents Form 9/77)*	" "
Request for substantive examination *(Patents Form 10/77)*	" "
Any other documents *(please specify)*	" "

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 30/7/98

12. Name and daytime telephone number of person to contact in the United Kingdom Tony Avison 01235 862122

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.*

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A Dilator

This disclosure describes a medical dilation device which may be used to dilate an occluded conduit, expand a stent or facilitate circumferential conformity when fitting a tubular graft inside a vessel residing in a living organism. The dilator consists of a series of wires formed into a geometry that can be similar to the dilatory balloons commonly used for luminal dilation's in a living organism.

Percutaneous Transluminal Coronary Angioplasty (PTCA) is a well known technique, commonly used in clinical maintenance or repair of certain fluid carrying vessels within a living organism. The technique requires the hydraulic expansion of a compliant balloon which is sited in a vessel that requires radial expansion.

PTCA which is specific to the dilation of coronary arteries, is the technique that has been applied to other conduits requiring dilation. Equally, a stent used as a conduit support structure may be used to continually support a dilated vessel or graft, ensuring luminal patency of said vessel or graft.

Stents [1] well known in the art, are generally metal constructions with perforated walls that may be radially expanded when positioned in the lumen of an occluded vessel by placing a balloon inside a stent and inflating the balloon. This increases the diameter of the stent which plastically deforms due to balloon inflation. Also, the placement of grafts and graft-stents combinations within a natural vessel, can benefit from an internally expanding balloon to urge the outer surface of the graft or graft-stent in intimate contact with the inner wall of the said vessel.

PCTA balloons may be inflated with hydraulic media using pressures up to 20 Atmosphere but, the balloon dimension may be such that the force with which a balloon expands may be less than that required to effect suitable radial expansion. For example, in

the case of fibrous lesions inside a vein, the fibrous material can be tough and tenacious resisting dilatory efforts presented by the balloon. The force required to expand the lumen of a vein may be beyond the force available from an inflatable balloon. There is also a danger of rupture, leakage or bursting of the balloon when used at relatively high pressure [2].

When dilation balloons are employed in arterial vessels, as they become fully dilated, blood flow in the artery is prevented or severely limited; ischemic problems may arise if blood flow is curtailed for extended period. This is particularly relevant for vessels associated directly with the cardiovascular system such as the coronary arteries. A wire-form balloon will not fully occlude the blood vessel; a reduction in volumetric through-put will occur due to the presence of both device delivery catheter and the wire-form balloon but in the case of a typical coronary artery, significant blood flow, sufficient to limit ischemic problems are possible.

Here presented is an improvement to the hydraulically inflated balloon. It employs direct mechanical connections rather than fluid pressure to expand a vessel, stent or graft or graft stent.

The construction of the dilation device consists of a plurality of wires (5), or thin strips, preferably made from a super elastic alloy, pre-formed into a substantially ellipsoidal (7) shape with one end open (9) and extended (8), the other end which is the leading or proximal end, terminates with the plurality of wire joined together by means of welding (10), crimping with a bush (11) or binding with a suitable wire or cord (12). The wires are configured with suitable elastic recovery properties so that they may be deformed and constrained to a minimised volume for introduction and transportation within a living organism. This is achieved by pulling the wire-form inside a sheath (13 - 16). If the constraining influence is removed, the wires resume a shape by elastic recovery. The restraining mechanism is a sheath of suitable dimensions so that the wires may be drawn into their retaining and constraining sheath (6), by drawing them into the sheath by

means of small tube (20), preferably a super elastic alloy as described. The tube is connected to each of the terminal ends of the wire-form balloon by welding, riveting or hard soldering.

Another elastically deformable wire (19), is positioned inside the tube (20) and connected to the leading edge of the wire-form balloon by welding, binding or by a crimped bush. The wire (19) can slide freely through the tube (20).

A nominal outer envelope diameter of the wire-form assembly is established by virtue of the elastic shape recovery of each wire-form element.

The unconstrained, elastic recovery of the wire-form may have sufficient hoop energy to effectively expand a stent or graft or natural vessel but, by utilising a wire to pull the end tip of the wire-form balloon and at the same time preventing the trailing-end of the device from moving, the wire-form can adopt an increase in its diametrical envelope. Equally, the wire-form envelope may be reduced by preventing the pulling wire (19) from moving while pulling the tube (20), to a pre-determined position. This enables one wire-form device to be used for dilation purposes within vessels of different diameters. The range of dilation diameters required would be from 4.0mm to 30.0mm.

The geometry of the wire-form balloon is preferably ellipsoidal in section although the shape may be configured for particular medical situations: For example, coronary occlusive disease which requires dilation of the vessels to re-instate luminal patency, should have a nominal diameter in an adult and when in good condition of approximately 4.0mm. However, the length of said lesions are typically up to 20mm. A wire-form balloon for this task will be long but relatively small in diameter. Tumorous growth in the oesophagous which may need dilation and stent support as a palliative measure, requires a wire-form with a different diameter-to-length relationship.

A preferred embodiment of a wire-form balloon consists of a flexible tube or catheter (6), containing wires having a predetermined shape when unconstrained (7). Said wires may be drawn into said flexible tube and constrained within the volume of the sheath. The geometry, in plan of the wire form consists of a series of arms radiating outwards (4), from the centre of the wire-form device. The number of said arms radiating outwards can be arranged from a minimum of two to a maximum of twenty.

The wire-forms, preferably constructed from super-elastic shape memory alloy, such as nickel-titanium, or nickel-titanium-copper or nickel-titanium-copper-chromium, may be drawn within the lumen of said sheath by means of a pulling tube (20). Elastic shape recovery of the wire-forms may be sufficient to effect suitable vessel dilation; additional expansion may be facilitated by pulling the proximal end of the wire-form balloon, normal to its long axis while constraining the distal ends of the wire-forms. This expands the diameter of the wire-form (21), reducing its length.

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:-

Fig. 1. Is a schematic representation of the wire-form dilator in plan (4) and a side view (5), showing the delivery catheter (6).

Fig. 2. Shows schematically, a single wire-form element (7 - 9), wire-form deployment and envelope expansion mechanism, in the from of a pulling wire (19), and pushing\pulling tube (20).

Fig 3. Illustrates schematically, the wire-form being drawn into its sheath or catheter. (13 - 16).

Fig 4. Illustrates schematically, the use of the pulling wire (19), pushing\pulling tube (20), to increase the wire-form envelope diameter (21)

Ref:

[1] Coronary Stenting for the Treatment of Restenosis After Percutaneous Transluminal Coronary Angioplasty.
Michael Haude MD. Raimund Erbel, MD
University of Essen, Cardiology Department.
Journal. Of Interventional Cardiology Vol.7 No4 1994.

[2]. A New platinum Balloon-Expandable Stent (Angiostent®) Mounted on a High Pressure Balloon: Acute and Late Results in an Atherogenic Swine Model.
Ziyad M. Hijaz, MD, MPH, Munther Homoud, MD Mark J. Aronvitz, BA,
John J. Smith, MD PhD, Gary Faler, MD.
Dept. Of Paediatrics, Medicine & Pathology, Tufts University School of Medicine, Boston Massachusetts.
Jour. Invasive Cardiology. 1995;7:127-134

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Fig. 1

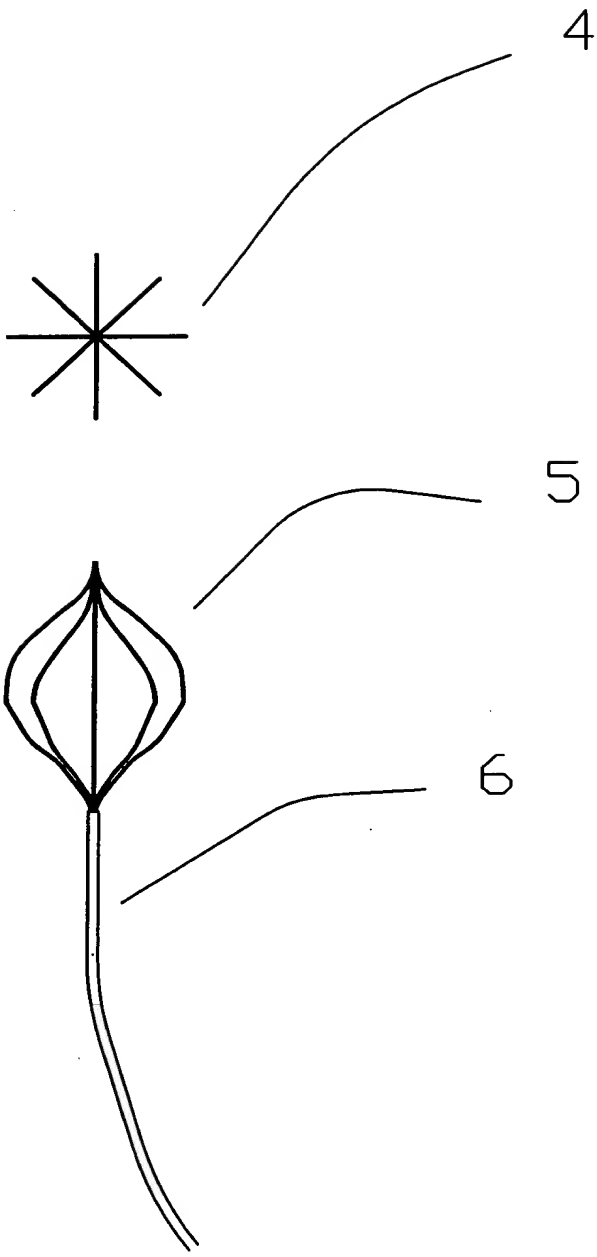
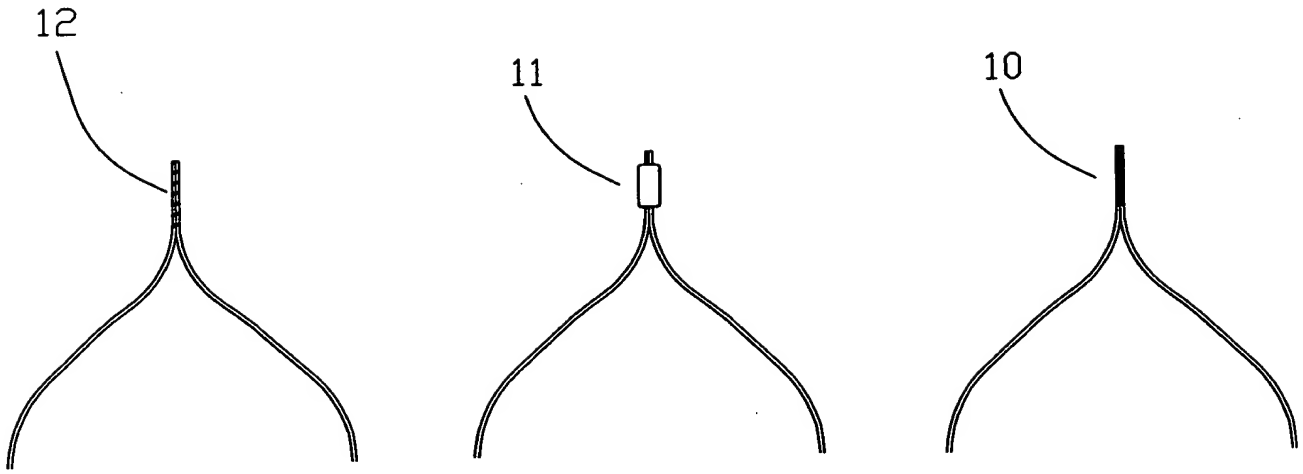
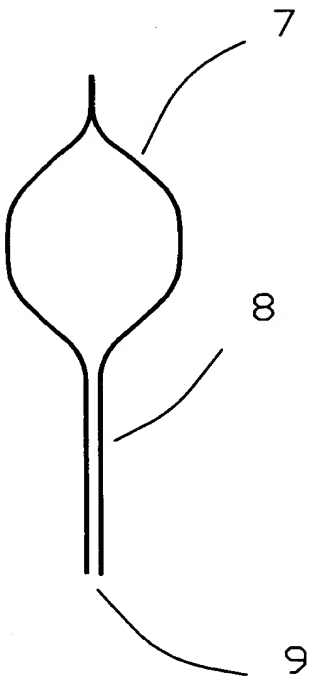


Fig 2





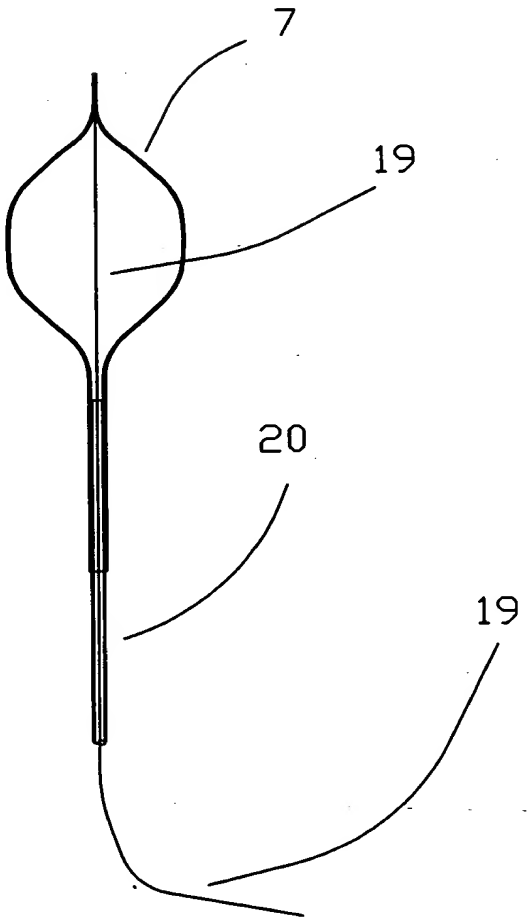


Fig 3.

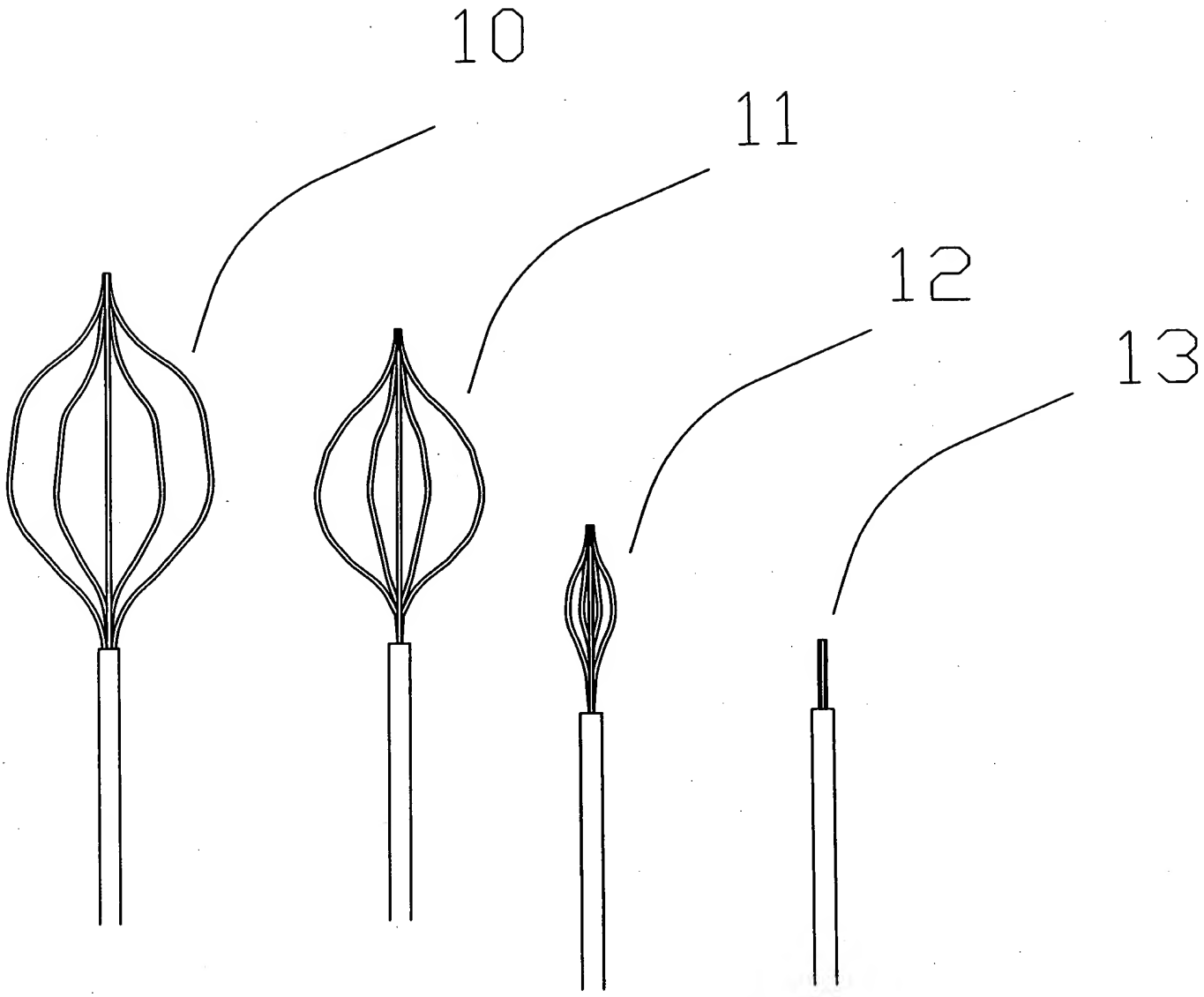
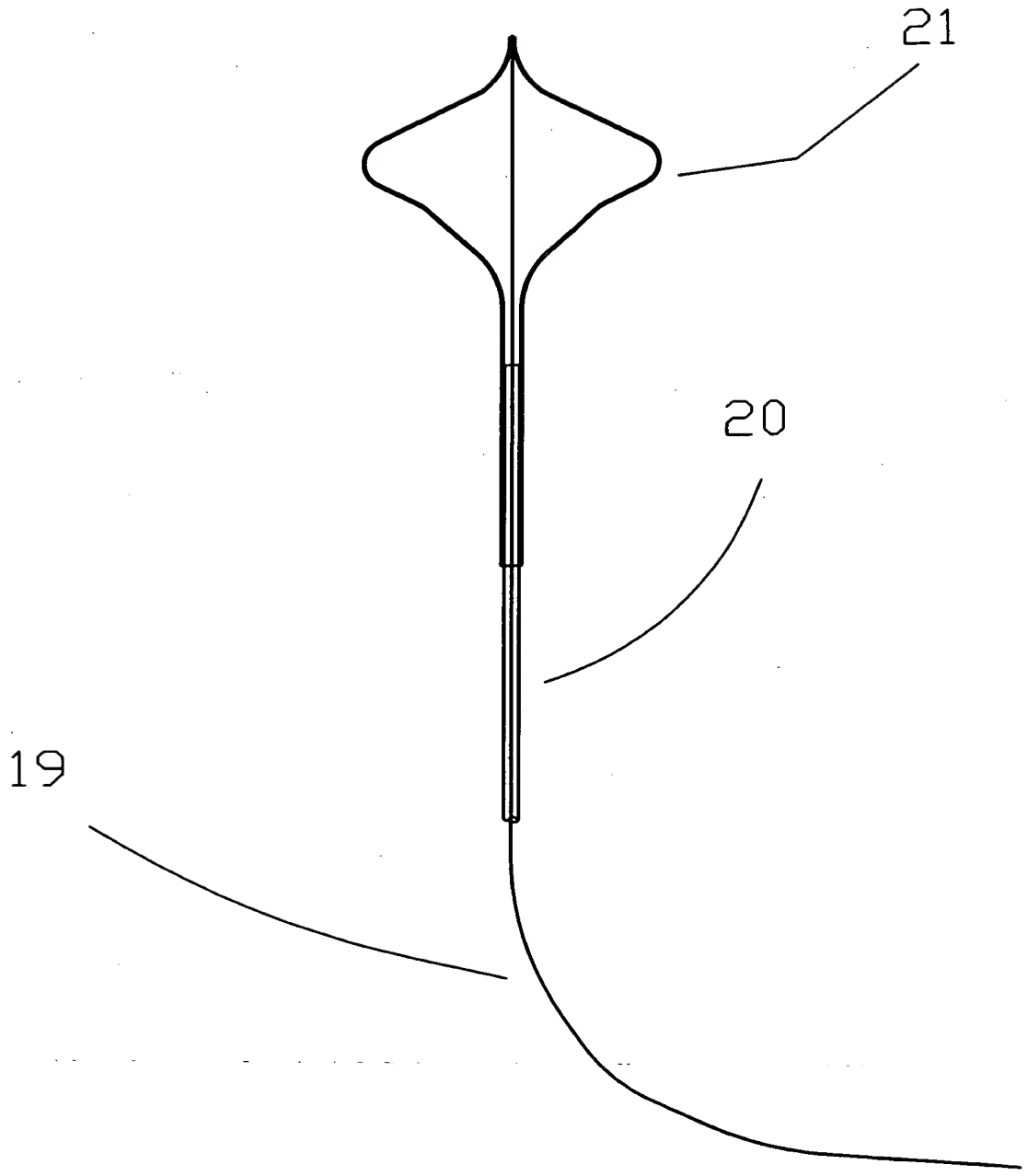


Fig 4



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